Initial Approval: July 11, 2018
Revised Dated: July 8, 2020; January 8, 2020; April 10, 2019

CRITERIA FOR PRIOR AUTHORIZATION

Hepatitis C Agents

BILLING CODE TYPE For drug coverage and provider type information, see the KMAP Reference Codes webpage.

MANUAL GUIDELINES Prior authorization will be required for all current and future dose forms available. All medication-specific criteria, including drug-specific indication, age, and dose for each agent is defined in table 1 below.

Elbasvir/grazoprevir (Zepatier®)
Glecaprevir/pibrentasvir (Mavyret®)
Ledipasvir/sofosbuvir (Harvoni®)
Ombitasvir/Paritaprevir/Ritonavir/Dasabuvir (Viekira Pak™)
Sofosbuvir (Sovaldi®)
Sofosbuvir/velpatasvir (Epclusa®)
Sofosbuvir/velpatasvir/voxilaprevir (Vosevi®)

CRITERIA FOR TREATMENT (MUST MEET ALL OF THE FOLLOWING):
**Patients new to the plan will be allowed to continue previous hepatitis C regimen (max of up to the duration listed below)*

- Must be approved for the indication, age, genotype, and not exceed medication-specific quantity limit and duration of therapy listed in Table 1 and 2.[1-8]
- For all agents listed, the preferred PDL drug, if applicable, which treats the PA indication, is required unless the patient meets the non-preferred PDL PA criteria.
- Patient has a pre-treatment detectable HCV RNA level drawn and results are submitted with PA request.
- Patient must not have a history of illicit intravenous (IV) substance use within the past 3 months.
- Prescriber must attest that the patient will be tested for evidence of current or prior hepatitis B virus (HBV) infection by measuring hepatitis B surface antigen (HBsAg) and hepatitis B core antibody (anti-HBc) before initiating HCV treatment.[1-8]
- Prescriber must attest that the patient has been fully educated on their treatment and the importance of medication adherence and is motivated to be adherent to the full course of treatment.
- If the request is for elbasvir/grazoprevir and the patient has genotype 1a infection: Prescriber must provide the patient's baseline testing results for NS5A resistance-associated polymorphisms.[8]

LENGTH OF APPROVAL: Up to the total number of approved weeks based upon FDA labeling in Table 2.

CRITERIA FOR TREATMENT-EXPERIENCED (WITH PREVIOUS DAA) PATIENTS: (must meet all of the following)

- Patient must meet all criteria for treatment approval above.
- Must be prescribed by or in consultation with a hepatologist, gastroenterologist, or infectious disease specialist.
- The requested agent is FDA-approved as therapy for treatment-experienced patients.[1-8]
- Patient has not been previously treated with and failed the requested regimen (regimen should include another DAA in which the patient has not failed).[1]

PA Criteria

- Prescriber has provided details that the patient has a documented presence of detectable HCV RNA at least 12 weeks after completing treatment.[1] Prescriber has provided details that re-infection has been ruled out.
    - Patients who previously achieved SVR that have HCV recurrence due to reinfection may be managed as an initial infection.[1]

LENGTH OF APPROVAL: Up to the total number of approved weeks based upon FDA labeling in Table 2.

FOR DRUGS THAT HAVE A CURRENT PA REQUIREMENT, BUT NOT FOR THE NEWLY APPROVED INDICATIONS, FOR OTHER FDA-APPROVED INDICATIONS, AND FOR CHANGES TO AGE REQUIREMENTS NOT LISTED WITHIN THE PA CRITERIA:

- **THE PA REQUEST WILL BE REVIEWED BASED UPON THE FOLLOWING PACKAGE INSERT INFORMATION: INDICATION, AGE, DOSE, AND ANY PRE-REQUISITE TREATMENT REQUIREMENTS FOR THAT INDICATION.**

LENGTH OF APPROVAL (INITIAL AND RENEWAL): Up to the total number of approved weeks based upon FDA labeling in the package insert.

Table 1. FDA-approved age and indications for Hepatitis C Agents.[2-8]

Agents	Indication(s)	Age/Weight
Antihepaciviral NS3/4A Protease Inhibitor and NS5A Inhibitor Combination		
Elbasvir/Grazoprevir (Zepatier®)	Chronic hepatitis C genotype 1 or 4 infection without cirrhosis or with compensated cirrhosis (Child-Pugh A)	≥ 18 years
Glecaprevir/pibrentasvir (Mavyret®)	Chronic hepatitis C genotype 1, 2, 3, 4, 5, or 6 infection without cirrhosis or with compensated cirrhosis (Child-Pugh A)	≥ 12 years or weighing ≥ 45 kg
Antihepaciviral NS3/4A Protease Inhibitor and NS5A Inhibitor and NS5B Inhibitor Combination		
Ombitasvir/Paritaprevir/ Ritonavir/Dasabuvir (Viekira Pak™)	Chronic hepatitis C genotype 1a or 1b infection without cirrhosis or with compensated cirrhosis (Child-Pugh A)	≥ 18 years
Sofosbuvir/velpatasvir/ voxilaprevir (Vosevi®)	Chronic hepatitis C genotype 1, 2, 3, 4, 5, or 6 infection without cirrhosis or with compensated cirrhosis (Child-Pugh A)	≥ 18 years
Antihepaciviral NS5A Inhibitor and NS5B Inhibitor Combination		
Ledipasvir/sofosbuvir (Harvoni®)	Chronic hepatitis C genotype 1, 4, 5, or 6 infection	≥ 3 years
Sofosbuvir/Velpatasvir (Epclusa®)	Chronic hepatitis C genotype 1, 2, 3, 4, 5, or 6 infection	≥ ~~18~~6 years or weighing ≥ 17 kg
Antihepaciviral NS5B Inhibitor		
Sofosbuvir (Sovaldi®)	Chronic hepatitis C genotype 1, 2, 3, or 4 infection in adults without cirrhosis or with compensated cirrhosis (Child-Pugh A) as a component of a combination antiviral treatment regimen. Chronic hepatitis C genotype 2 or 3 infection in pediatrics without cirrhosis or with compensated cirrhosis (Child-Pugh A) in combination with ribavirin.	≥ 18 years ≥ 3 years

Table 2. Treatment Regimen and Duration by Genotype.[2-8]

Agents	Patient Population	Treatment Duration
Antihepaciviral NS3/4A Protease Inhibitor and NS5A Inhibitor Combination		
Elbasvir/Grazoprevir (Zepatier®)	Genotype 1a and treatment-naïve or peginterferon/ribavirin-experienced without cirrhosis or with compensated cirrhosis (Child-Pugh class A) without baseline NS5A polymorphisms (at amino acid positions 28, 30, 31, or 93). Genotype 1b and treatment-naïve or peginterferon/ribavirin-experienced without cirrhosis or with compensated cirrhosis (Child-Pugh class A). Genotype 4 and treatment-naïve without cirrhosis or with compensated cirrhosis (Child-Pugh class A).	One tablet daily (elbasvir 50 mg-grazoprevir 100 mg per day) for 12 weeks.
	Genotype 1a or 1b and treatment-experienced with peginterferon/ribavirin/HCV NS3/4A protease inhibitor without cirrhosis or with compensated cirrhosis (Child-Pugh class A).	One tablet daily (elbasvir 50 mg-grazoprevir 100 mg per day) for 12 weeks in combination with ribavirin.
	Genotype 1a and treatment-naïve or peginterferon/ribavirin-experienced without cirrhosis or with compensated cirrhosis (Child-Pugh class A) with baseline NS5A polymorphisms (at amino acid positions 28, 30, 31, or 93). Genotype 4 and treatment-experienced with peginterferon/ribavirin without cirrhosis or with compensated cirrhosis (Child-Pugh class A).	One tablet daily (elbasvir 50 mg-grazoprevir 100 mg per day) for 16 weeks in combination with ribavirin.
Glecaprevir/pibrentasvir (Mavyret®)	Genotype 1, 2, 3, 4, 5, 6, and treatment-naïve without cirrhosis or with compensated cirrhosis (Child-Pugh class A). Genotype 1, 2, 4, 5, 6, and treatment-experienced with peginterferon/ribavirin and/or sofosobuvir (without prior treatment with an NS5A inhibitor or NS3/4A protease inhibitor) without cirrhosis.	Three tablets daily (glecaprevir 300 mg-pibrentasvir 120 mg per day) for 8 weeks.
	Genotype 1 and treatment-experienced with an NS3/4A protease inhibitor (without prior treatment with an NS5A inhibitor) without cirrhosis or with compensated cirrhosis (Child-Pugh class A). Genotype 1, 2, 4, 5, 6, and treatment-experienced with peginterferon/ribavirin and/or sofosobuvir (without prior treatment with an NS5A inhibitor or NS3/4A protease inhibitor) with compensated cirrhosis (Child-Pugh class A).	Three tablets daily (glecaprevir 300 mg-pibrentasvir 120 mg per day) for 12 weeks.

Agents	Patient Population	Treatment Duration
	Genotype 1, 2, 4, 5, 6, and liver or kidney transplant recipients without cirrhosis or with compensated cirrhosis (Child-Pugh class A).	
	Genotype 1 and treatment-experienced with an NS5A inhibitor (without prior treatment with an NS3/4A protease inhibitor) without cirrhosis or with compensated cirrhosis (Child-Pugh class A). Genotype 3 and treatment-experienced with peginterferon/ribavirin and/or sofos~~o~~buvir ((without prior treatment with an NS5A inhibitor or NS3/4A protease inhibitor) without cirrhosis or with compensated cirrhosis (Child-Pugh class A). Genotype 1 and liver or kidney transplant recipient's treatment-experienced with an NS5A inhibitor (without prior treatment with an NS3/4A protease inhibitor) without cirrhosis or with compensated cirrhosis (Child-Pugh class A). Genotype 3 and liver or kidney transplant recipient's treatment-experienced with peginterferon/ribavirin and/or sofos~~o~~buvir (without prior treatment with an NS5A inhibitor or NS3/4A protease inhibitor) with compensated cirrhosis (Child-Pugh class A).	Three tablets daily (glecaprevir 300 mg-pibrentasvir 120 mg per day) for 16 weeks.
Antihepaciviral NS3/4A Protease Inhibitor and NS5A Inhibitor and NS5B Inhibitor Combination		
Ombitasvir/Paritaprevir/ Ritonavir/Dasabuvir (Viekira Pak™)	Genotype 1a without cirrhosis	Four tablets daily (ombitasvir 25 mg-paritaprevir 150 mg-ritonavir 100 mg-dasabuvir 500 mg per day) with concomitant ribavirin for 12 weeks.
	Genotype 1a with compensated cirrhosis	Four tablets daily (ombitasvir 25 mg-paritaprevir 150 mg-ritonavir 100 mg-dasabuvir 500 mg per day) with concomitant ribavirin for 24 weeks. * Medication administered with ribavirin for 12 weeks may be considered for patients with prior PEG~~peg~~-IFN and who partially responded.

Agents	Patient Population	Treatment Duration
	Genotype 1b without cirrhosis or with compensated cirrhosis	Four tablets daily (ombitasvir 25 mg-paritaprevir 150 mg-ritonavir 100 mg-dasabuvir 500 mg per day) for 12 weeks.
Sofosbuvir/velpatasvir/ voxilaprevir (Vosevi®)	Genotype 1, 2, 3, 4, 5, 6, and treatment-experienced with an NS5A inhibitor without cirrhosis or with compensated cirrhosis (Child-Pugh class A). Genotype 1a or 3, and treatment-experienced with sofosbuvir (without prior treatment with an NS5A inhibitor) without cirrhosis or with compensated cirrhosis (Child-Pugh class A).	One tablet daily (sofosbuvir 400 mg-v~~a~~elpatasvir 100 mg-voxilaprevir 100 mg per day) for 12 weeks.
Antihepaciviral NS5A Inhibitor and NS5B Inhibitor Combination		
Ledipasvir/sofosbuvir (Harvoni®)	Genotype 1 and treatment-naïve without cirrhosis or with compensated cirrhosis (Child-Pugh class A). Genotype 1 and treatment-experienced (with peginterferon alfa +/- ribavirin based regimen with or without an HCV protease inhibitor) without cirrhosis. Genotype 4, 5, 6, and treatment-naïve or treatment-experienced (with peginterferon alfa +/- ribavirin based regimen with or without an HCV protease inhibitor) without cirrhosis or with compensated cirrhosis (Child-Pugh class A).	Pediatrics weighing ≥ 35 kg and adults: one tablet ~~or packet~~ daily (ledipasvir 90 mg-sofosbuvir 400 mg per day) for 12 weeks. Pediatrics weighing 17 to < 35 kg: one tablet or packet daily (ledipasvir 45 mg-sofosbuvir 200 mg per day) for 12 weeks. Pediatrics weighing < 17 kg: one tablet or packet daily (ledipasvir 33.75 mg-sofosbuvir 150 mg per day) for 12 weeks.
	Genotype 1 and treatment-naïve or treatment-experienced (with peginterferon alfa +/- ribavirin based regimen with or without an HCV protease inhibitor) with decompensated cirrhosis (Child-Pugh class B or C). Genotype 1 or 4, and treatment-naïve or treatment-experienced (with peginterferon alfa +/- ribavirin based regimen with or without an HCV protease inhibitor) liver transplant recipients without cirrhosis or with compensated cirrhosis (Child-Pugh class A).	Pediatrics weighing ≥ 35 kg and adults: one tablet ~~or packet~~ daily (ledipasvir 90 mg-sofosbuvir 400 mg per day) with concomitant ribavirin for 12 weeks. Pediatrics weighing 17 to < 35 kg: one tablet or packet daily (ledipasvir 45 mg-sofosbuvir 200 mg per day) with concomitant ribavirin for 12 weeks. Pediatrics weighing < 17 kg: one tablet or packet daily

Agents	Patient Population	Treatment Duration
		(ledipasvir 33.75 mg-sofosbuvir 150 mg per day) with concomitant ribavirin for 12 weeks.
	Genotype 1 and treatment-experienced (with peginterferon alfa +/- ribavirin based regimen with or without an HCV protease inhibitor) with compensated cirrhosis (Child-Pugh class A).	Pediatrics weighing ≥ 35 kg and adults: one tablet ~~or packet~~ daily (ledipasvir 90 mg-sofosbuvir 400 mg per day) for 24 weeks. Pediatrics weighing 17 to < 35 kg: one tablet or packet daily (ledipasvir 45 mg-sofosbuvir 200 mg per day) for 24 weeks. Pediatrics weighing < 17 kg: one tablet or packet daily (ledipasvir 33.75 mg-sofosbuvir 150 mg per day) for 24 weeks.
Sofosbuvir/Velpatasvir (Epclusa®)	Genotype 1, 2, 3, 4, 5, 6, and treatment-naïve or peginterferon/ribavirin-experienced with or without an HCV NS3/4A protease inhibitor (boceprevir, simeprevir, or telaprevir) without cirrhosis or with compensated cirrhosis (Child-Pugh class A).	Pediatrics weighing ≥ 30 kg and adults: One tablet daily (sofosbuvir 400mg-velpatasvir 100mg per day) for 12 weeks. Pediatrics weighing 17 to < 30 kg: One tablet daily (sofosbuvir 200 mg-velpatasvir 50mg per day) for 12 weeks.
	Genotype 1, 2, 3, 4, 5, 6, and treatment-naïve and treatment-experienced with or without an HCV NS3/4A protease inhibitor with decompensated cirrhosis (Child-Pugh B and C).	Pediatrics weighing ≥ 30 kg and adults: One tablet daily (sofosbuvir 400mg-velpatasvir 100mg per day) with concomitant ribavirin for 12 weeks. Pediatrics weighing 17 to < 30 kg: One tablet daily (sofosbuvir 200 mg-velpatasvir 50mg per day) with concomitant ribavirin for 12 weeks.
Antihepaciviral NS5B Inhibitor		
Sofosbuvir (Sovaldi®)	Adults and pediatrics with genotype 2 and treatment-naïve or treatment-experienced (with interferon-based	Pediatrics weighing ≥ 35 kg and adults: One tablet ~~or~~

Agents	Patient Population	Treatment Duration
	regimen with or without ribavirin) without cirrhosis or with compensated cirrhosis (Child-Pugh class A).	~~packet~~ daily (sofosbuvir 400 mg per day) with concomitant ribavirin for 12 weeks. Pediatrics weighing 17 to < 35 kg: One tablet or packet daily (sofosbuvir 200 mg per day) with concomitant ribavirin for 12 weeks. Pediatrics weighing < 17 kg: One tablet or packet daily (sofosbuvir 150 mg per day) with concomitant ribavirin for 12 weeks.
	Adults with genotype 1 or 4, and treatment-naïve without cirrhosis or with compensated cirrhosis (Child-Pugh class A).	Pediatrics weighing ≥ 35 kg and adults: One tablet ~~or packet~~ daily (sofosbuvir 400 mg per day) with concomitant peginterferon and ribavirin for 12 weeks. Pediatrics weighing 17 to < 35 kg: One tablet or packet daily (sofosbuvir 200 mg per day) with concomitant peginterferon and ribavirin for 12 weeks. Pediatrics weighing < 17 kg: One tablet or packet daily (sofosbuvir 150 mg per day) with concomitant peginterferon and ribavirin for 12 weeks.
	Adults and pediatrics with genotype 3 and treatment-naïve or treatment-experienced (with interferon-based regimen with or without ribavirin) without cirrhosis or with compensated cirrhosis (Child-Pugh class A).	Pediatrics weighing ≥ 35 kg and adults: One tablet ~~or packet daily~~ (sofosbuvir 400 mg per day) with concomitant ribavirin for 24 weeks. Pediatrics weighing 17 to < 35 kg: One tablet or packet daily (sofosbuvir 200 mg per day)

PA Criteria

Agents	Patient Population	Treatment Duration
		with concomitant ribavirin for 24 weeks. Pediatrics weighing < 17 kg: One tablet or packet daily (sofosbuvir 150 mg per day) with concomitant ribavirin for 24 weeks.

Notes:

- Harvoni (ledipasvir/sofosbuvir) for 8 weeks can be considered in treatment-naïve genotype 1 patients without cirrhosis who have pretreatment HCV RNA < 6 million IU/mL.[3]
- Zepatier: Testing patients with HCV genotype 1a infection for the presence of virus with NS5A resistance-associated polymorphisms is recommended prior to treatment initiation to determine regimen and duration. Sustained virologic response rates were lower after 12 weeks in genotype 1a-infected patients with one or more baseline NS5A resistance-associated polymorphisms at amino acid positions 28, 30, 31, or 93.[8]
- Daklinza (daclatasvir) was discontinued by BMS in June 2019.
- Technivie (ombitasvir/paritaprevir/ritonavir) was discontinued by Abbvie in January 2019.
- Viekira XR (ombitasvir/paritaprevir/ritonavir/dasabuvir) was discontinued by Abbvie in January 2019.
- Olysio (simeprevir) was discontinued by Janssen in May 2018.
- Victrelis (boceprevir) was discontinued by Merck in December 2015.
- Incivek (telaprevir) was discontinued by Vertex in October 2014.

References

1. AASLD-IDSA. Recommendations for testing, managing, and treating hepatitis C. http://www.hcvguidelines.org. Accessed ~~November~~ May ~~30~~26, 20~~19~~20. Available at: https://www.hcvguidelines.org/
2. Epclusa (sofosbuvir/velpatasvir) [prescribing information]. Foster City, CA: Gilead Sciences, Inc; ~~November~~ March 20~~19~~20.
3. Harvoni (ledipasvir/sofosbuvir) [prescribing information]. Foster City, CA: Gilead Sciences, Inc; ~~November~~ March 20~~19~~20.
4. Mavyret (glecaprevir/pibrentasvir) [prescribing information]. North Chicago, IL: AbbVie Inc; ~~September~~ May 20~~19~~20.
5. Sovaldi (sofosbuvir) [prescribing information]. Foster City, CA: Gilead Sciences, Inc; ~~September~~ March 20~~19~~20.
6. Viekira Pak (ombitasvir/paritaprevir/ritonavir/dasabuvir) [prescribing information]. North Chicago, IL: AbbVie Inc; December 2019.
7. Vosevi (sofosbuvir/velpatasvir/voxilaprevir) [prescribing information]. Foster City, CA: Gilead Sciences Inc; November 2019.
8. Zepatier (elbasvir and grazoprevir) [prescribing information]. Whitehouse Station, NJ: Merck Sharp & Dohme Corp; December 2019.

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DRUG UTILIZATION REVIEW COMMITTEE CHAIR

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DATE

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PHARMACY PROGRAM MANAGER
DIVISION OF HEALTH CARE FINANCE
KANSAS DEPARTMENT OF HEALTH AND ENVIRONMENT

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DATE